

## REMARKS

It is noted that claims 9 and 10 are allowable.

It is respectfully requested that this amendment be entered. If this amendment is entered claims 1, 2, 4-11, 14, 15 and 17 will be in this application. Claims 1, 2, 4, 10, 11, 15 and 17 will have been amended. Claims 3, 12, 13 and 16 will have been canceled.

Support for a controlled release composition for oral administration having a fast release fraction and an extended release fraction with Nimesulide being present in the fast release and in the extended release fraction is found at, *inter alia*, page 8, lines 3-4, 11-13 and examples 10 and 11 of the specification.

Support for the term release controlling materials is based on the fact that the materials are used to control release of the active ingredient.

The Examiner has rejected claims 1-8, 11 and 14-17 as being anticipated Singh et al. (US 5,876,751). Applicants respectfully traverse this rejection.

Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *In re Paulsen*, 30 F.3d 1475, 31 USPQ 1671 (Fed. Cir. 1994). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991).

Singh et al. discloses specifically a pharmaceutical composition of Diclofenac free acid, Fenpiverinium Bromide and Pitofenone hydrochloride. It does not teach a controlled release formulation of nimesulide as a single active drug in a unit dose.

Singh does not disclose that a composition can comprise both a fast release fraction and extended release fraction. Singh teaches modified, sustained, controlled and timed release formulations. In addition, Singh does not disclose that


Singh et al. does not disclose a controlled release pharmaceutical composition of nimesulide which has a fast release fraction and an extended release fraction wherein nimesulide is present in the fast release fraction and in the extended release fraction.

Therefore, since each and every element of the claimed invention is not disclosed in Singh et al. claims 1-8, 11 and 14-17 cannot be anticipated.

Therefore, it is respectfully requested that this rejection be withdrawn.

Accordingly, applicants submit that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted

A handwritten signature in black ink, appearing to read 'Janet I. Cord', written over a horizontal line.

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